Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed January 19, 2007. Currently, claims 38-58 remain pending. Claims 38-58 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Priority Objection

On page 2 of the Office Action, the Examiner objects to the priority reference of the present application. The Examiner states, "[t]he reference to application 10/135,006 at the beginning of the Specification should be updated to reflect that the application is now abandoned." However, after careful review, Applicant believes that application 10/135,006 is not abandoned and is now issued U.S. Patent No. 6,814,740 and that application 10/341,170 is now abandoned. Accordingly, Applicant has amended the beginning of the Specification preceding "Field of the Invention" to recite, "This is a divisional of copending Application Serial No. 10/341,170 filed January 13, 2003, now abandoned, which in turn is a continuation of Application Serial No. 10/135,006 filed on April 30, 2002, now U.S. Patent No. 6,814,740, which in turn is a continuation of Application Serial No. 09/801,186 filed on March 8, 2001, now U.S. Patent No. 6,402,761, which in turn is a continuation of Application Serial No. 09/427,553 filed October 27, 1999, now U.S. Patent No. 6,217,589."

Claim Rejections – 35 USC § 102

On page 2 of the Office Action, claims 38-44 and 46-57 were rejected under 35 U.S.C. 102(b) as being anticipated by Gibbs et al. (U.S. Patent No. 5,330,482). After careful review, Applicant must respectfully disagree.

Turning to claim 38, which recites:

> 38. (Previously Presented) A medical device for use in a body lumen, comprising: a self-expanding body formed from struts having a compressed state and an expanded state; the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body; and a sheath at least partially enclosing the body in the compressed state.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (See MPEP § 2131). Accordingly, Gibbs et al. must teach each and every element in as complete detail as is contained in claim 38.

Gibbs et al. appears to disclose a wire basket stone extractor. The extractor incorporates the use of a composite wire having an inner monofilament wire (11) of nitinol material surrounded by a stranding (12) of five or six stainless steal wires. (See column 3, lines 17-25). The shape memory material used in extraction wires (10) and (20) is a nickel titanium allow known as nitinol, which is composed of about 55% Ni and 44% Ti, with trace elements of Cu (150 ppm), Fe (110 ppm), and Mn (21 ppm), having the characteristics of superelasticity. (See column 3, lines 49-55). Nowhere does Gibbs et al. appear to disclose, "the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body", as recited in claim 38. In contrast, Gibbs et al. recites "whereby they (nitinol wires) exhibit a superelastic tendency to retain the shape in which they are formed when heat is applied to a suitable presorting temperature". (Column 3, lines 55-57). Therefore, the body is not cold formed, as recited in claim 38.

In the Office Action, the Examiner asserts that the device disclosed by Gibbs et al. is formed of nickel-titanium alloy and is considered to comprise the same characteristics as is contained in the claims. From this, it appears that the Examiner is asserting that the claimed limitations are inherent in Gibbs et al. In order to establish inherency, the missing descriptive matter must be necessarily present in the reference and that it would be so recognized by persons of ordinary skill. (See MPEP § 2131.01). After careful review, Applicant must respectfully disagree.

In fact, nickel-titanium alloys may have many different characteristics depending on how it is processed, such as, for example, nickel-titanium alloys may have superelastic characteristics or may have linear elastic characteristics. It is an advantage of superelastic materials that, after imparting the superelastic properties by proper processing, they may be highly strained (deformed), yet still regain their original shape upon release of the deforming stress. It is an advantage of common linear elastic materials that they can be conveniently and easily plastically deformed to a desired shape with relatively little strain.

The present invention discloses alloys that are highly elastic, i.e. have high strain prior to yield, although typically not as high as the maximum strain of superelastic materials, but are also easily plastically deformable. Such alloys are those that are precursors of superelastic alloys, i.e., they have the same chemical constituents as superelastic alloys, but have not been processed to impart the superelastic property.

Precursor alloys, when first cold drawn from ingots into raw elements of constant diameter occur in the martensite phase at room temperature, as opposed to the superelastic alloy themselves which are drawn while heating and occur in the austenite phase at room temperature. The springiness and straightness in the martensite precursors appears to be a result of the cold drawing process which gives the martensite crystalline structure a preferred orientation. The high strain and straightness of the material can be maintained as long as the material is not substantially heated. When excessively heated, the materials pass through a transition to the austenite phase and, after cooling and returning to the martensite phase, the crystalline orientation or work hardening of the martensite which was imparted during the initial cold drawing is lost, leading to a less straight, and sometimes somewhat less spring material. The temperature of the raw precursor element is kept below and, in some cases, well below, (e.g., room temperature,) the transition temperature from martensite to austenite during processing of the precursor material.

Furthermore, the present specification teaches away from using a superelastic material and, instead, teaches using a precursor alloy. The present description recites:

> [0006] Other baskets are formed from cable which includes a superelastic, sometimes referred to as shape memory, core wrapped with strands of stainless steel to surround the core. Nitinol is often used as the superelastic core in these devices. Nitinol is a specially heat-treated Titanium-Nickel (Ti--Ni) alloy, preferably approximately 55%/45% Nickel to Titanium (Ni--Ti). These baskets require heat treatment for the core to retain its

shape. Such a configuration allows for some improvement in performance when the baskets are used repeatedly and for lithotripsy because the superelastic core better retains its shape. (Emphasis added).

[0007] However, superelastic materials of this type experience phase transformations when subject to a certain level of stress loading. Lithotripsy often reaches these stress levels. Upon a phase transformation, the core of the cable stretches, rendering the device incapable of transferring force to the stone to complete the crushing process. Furthermore, the superelastic alloy has a greater reversible elongation than do the surrounding stainless steel strands. This results in a difference in deformation between the core and the surrounding strands leading to a permanent deformation of the cable. Such deformation results in an alteration of the basket shape, making it less desirable to use for its intended purpose. (Emphasis added).

[0011] The invention further includes a method of manufacturing the medical retrieval device including the steps of constructing a cable including a wire made of a precursor alloy to a superelastic material and forming a retrieval assembly by preforming the cable into a configuration adapted to capture and remove the foreign objects.

[0012] The precursor alloy according to the present invention exhibits a stress-strain curve having a linear relationship extending through a yield point with no phase transformation point. After the yield point, the stress-strain curve does not exhibit a substantially constant stress plateau as strain increases. Rather, the precursor alloy exhibits plastic deformation properties.

[0021] To accomplish these objectives and to overcome the problems associated with existing devices of this kind, a retrieval device of the present invention incorporates a precursor alloy into the stranded cable used for making the device. When subject to heat treatment, a precursor alloy results in the formation of a superelastic alloy. Prior to heat treatment, such a precursor alloy exhibits high elongation and a linear stress-strain relationship with a yield point. Because of these properties, the use of a precursor alloy in the manufacture of the device according to the present invention achieves greater strength, longer life, and ease in manufacture, as will be explained.

[0022] Unlike a superelastic alloy, a precursor alloy used in a medical retrieval device of the present invention exhibits a linear stress-strain relationship with a plastic yield point. For comparison purposes, schematics of the stress-strain curves for a superelastic alloy and a precursor alloy are shown in FIGS. 1a and 1b, respectively. As shown in FIG. 1a, as a superelastic alloy undergoes increased stress, strain increases

> to phase transformation point X. At X, the superelastic alloy transforms from an austenitic phase to a martensitic phase. Thereafter, stress remains substantially constant as strain increases, forming a substantially constant stress plateau P. Upon releasing the stress on the superelastic alloy, the reversibly deformable nature of the material allows it to return to its original length following curve Y in the Figure. The cycle shown often occurs repeatedly with no appreciable change in dimension or plastic deformation of the wire. Therefore, the superelastic alloy withstands a relatively large strain prior to the phase transformation point, and additional strain during the phase transformation, without plastic deformation. Furthermore, the phase transformation and reversible deformation of the superelastic alloy occurs at relatively low stress levels. During the superelastic alloy phase transformation, applied stress is absorbed by the alloy to facilitate the phase transformation, and is not available to be transferred to another object, such as a stone.
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> [0023] A precursor alloy material exhibits the stress-strain characteristics shown in FIG. 1b. Up to the plastic yield point Z, strain increases in a reversible manner as stress increases. That is, the precursor alloy returns to its normal configuration upon release of stresses prior to reaching plastic yield point Z. Moreover, the precursor alloy does not pass through a substantially constant stress plateau as does the superelastic alloy. At stresses above yield point Z, the precursor alloy becomes plastically and irreversibly deformed, unlike the superelastic alloy. As shown in FIGS. 1a and 1b, yield point Z of the precursor alloy generally occurs at higher stress levels than does phase transformation point X of the superelastic material. This enables the device of the present invention to transfer greater stress to stones during lithotripsy, as well as facilitating dilation of ducts. Accordingly, the inventive devices facilitate retrieval and removal, while maintaining shape and strength over repeated uses.
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> [0024] In addition to requiring heat treatment of the precursor alloy to produce the superelastic material, a conventional retrieval device also requires heat treatment during the formation of the basket so that the superelastic wires maintain their shape. In contrast, a result of the plastic yield point associated with a precursor alloy, the basket of the present device forms easily by mechanically bending the precursor alloy wire beyond its yield point and into shape. Sophisticated heat treatments are thus unnecessary in the manufacture of the inventive device.

(Emphasis added). As can be clearly seen, the present invention, as claimed in claim 38, does not include a superelastic nitinol material, as disclosed by Gibbs et al., but instead, discloses a cold-formed nickel-titanium alloy, or a precursor alloy. Therefore, clearly Gibbs et al. does not expressly or inherently disclose, "the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body", as recited in claim 38. Thus, claim 38 is believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 47, which recites:

> 47. (Previously Presented) A medical device for use in a body lumen, comprising: a self-expanding body formed from struts; the body including a cold formed nickel-titanium alloy, wherein the nickel-titanium alloy is in a martensitic phase when the body is stressed into a first shape and when the body is stress relieved to a second shape, and wherein the nickel-titanium alloy has a transformation temperature >37 degrees C.; and a sheath at least partially enveloping the body in its first shape.

For similar reasons given above, as well as others, claim 47 is believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection. Additionally, for similar reasons, as well as others, claims 48-52, which depend from claim 47 and include significant additional limitations, are believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 53, which recites:

> 53. (Previously Presented) A method of providing a medical device for use in a body lumen, comprising: providing struts including a cold formed nickel-titanium alloy; setting a transformation temperature >37 degrees C.; cold forming the struts into a body having a shape; stressing the body into a first shape wherein the nickel-titanium alloy is in a martensitic phase; providing a sheath; disposing the body in the first shape at least partially inside the sheath; and deploying the body from the sheath to stress relieve the body into a second shape, wherein the nickel-titanium alloy remains in the martensitic phase.

For similar reasons given above, as well as others, claim 53 is believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection. Additionally, for similar reasons, as well as others, claims 54-57, which depend from claim 53 and include significant additional limitations, are believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 USC § 103

On page 3 of the Office Action, claims 45 and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs et al. (U.S. Patent No. 5,330,482). After careful review, Applicant must respectfully disagree.

For similar reasons given above, as well as others, claims 45 and 58, which depend from claims 38 and 53, respectively, and include significant additional limitations, are believed to be patentable over Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, all pending claims, namely claims 38-58, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully Submitted,
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By his Attorney

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